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- (21) On application No.2000101000/14(001785)
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- (71) Applicant(s): Impulse Dynamics N.V.
- (51) IPC<sup>7</sup> A61N 1/00

To make possible further examination of the application, the Applicant is requested to present materials, documents, information related to the questions raised by the Examiner, the opinion related to the arguments, remarks and proposals given in the official action.

The response to this official action shall be presented within 2 months from the date of its receipt (article 21-8 of the Patent Law of the Russian Federation). The due date may be postponed on the applicant's request filed within this term and payment of a corresponding fee.

If the response is not filed in time, the application will be considered abandoned.

## QUESTIONS, ARGUMENTS, REMARKS, PROPOSALS

In accordance with Article 27(5) of the PCT, the patentability of the invention has been examined in accordance with the national Patent Law, i.e. in accordance with Article 4(2) of the Russian Patent Law. The Examiner notes that all the conditions for establishing the Convention priority in accordance with Rule 19.3.1 of the Russian Patent Rules are met by the Applicant and therefore the Convention priority of 16.07.97 is established.

After examining the claims and disclosure in relation to the claimed methods, the Examiner notes the following.

1. The words "for example" mentioned in claim 1 lead to an ambiguous interpretation of the scope of protection and therefore shall be deleted.

In accordance with Rule 3.3.2.5(1) of the Russian Patent Rules, a dependent claim shall comprise development and/or specification of the features of an independent claim by features defining the invention in a specific case of its implementation or use. Dependent claim 2 does not comply with the requirements of said Rule. In accordance with claim 1, the applied electric field reduces the mechanical activity at the location of a lesion, while in claim 2 it is indicated that the electric field is applied at the smooth muscle portion surrounding the lesion. Therefore, claim 2 contradicts claim 1. The Applicant shall eliminate the above contradiction.

There is also a discrepancy between the disclosure and claim 1. Thus, on p. 23 of the disclosure it is indicated that a sutured region of GI tract is fenced by applying an anastomosis button, i.e. the portion having a lesion is mechanically fenced. At the same time in claim 1 it is indicated that the fencing is realized by applying an electric field. Therefore the Applicant is requested to eliminate the above discrepancy by amending the disclosure or the claims without going beyond the scope of the original application materials.

In accordance with Rule 19.5.1(1) of the Rules, the possibility to implement the purpose to be served by the claimed subject-matter and indicated by the Applicant shall be confirmed. In this connection, the Examiner notes that examples confirming the possibility to implement the purpose indicated in claim 1 are absent from the application materials. The invention of claim 1 cannot be regarded as complying with the requirement of industrial applicability unless such examples are presented by the Applicant. The same relates to claims 4-7, 9-11, 15-19, 20, 21, 22, 70-73, 77-80 and 89-93.

The Examiner also notes that known is a method of blocking the mechanical activity of a stomach when treating intestinal polyposis, comprising electrocoagulating the polyp peduncle and administering peristalsis decreasing agents to prevent the formed crust from being injured (see RU 2078547 C1, 10.05.1997).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of a muscle by applying to it a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

Therefore, the invention claimed in claim 1 is not inventive in view of these documents.

2. The Examiner notes that also known is to block the bowel mechanical activity at acute diarrhea by using such a pharmacological agent as loperamide (Imodium) (see RU 2014844 C1, 30.06.1994, the disclosure).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle by applying to it a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

Therefore, the invention claimed in claim 4 is not inventive in view of these documents.

3. In accordance with Rule 3.3.2.5(1) of the Russian Patent Rules, a dependent claim shall comprise development and/or specification of the features of an independent claim by features defining the invention in a specific case of its implementation or use. Dependent claim 8 does not comply with the requirements of said Rule. Thus, in accordance with claim 7, the applied electric field reduces the motility of the end portion of a stoma, while in claim 8 it is indicated that the electric field is applied in such a way as to increase the motility of the stoma. Therefore, claim 8 contradicts claim 7. The Applicant shall eliminate the above contradiction.

The Examiner also notes that known is a method of controlling emptying a stoma comprising using an obturator and two lavan tapes which are situated in an empty space of a ring made of autoskin. The emptying of a stoma is achieved by unbinding the tapes and removing the obturator (see RU 2077273, 20.04.1997).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle by applying to it a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

Therefore, the invention claimed in claim 7 is not inventive in view of these documents.

4. The Examiner notes that the term "tension" mentioned in claim 11 is unidentifiable because it is unclear what tension is meant. The Applicant shall either cancel this feature from the claim, or indicate a document, published before the priority date of the present application, wherein this term was explained.

The technical essence of the invention claimed in claim 11 is unclear. Thus, since the applied electric field relaxes a portion of the colon, then the treatment is evidently directed to the elimination of constipations typical for this pathology. In accordance with the above, the Applicant measures a tension (?) in the portion of the colon, i.e. of the spastic colon, and applies an electric field when the tension further increases.

However, the spasm had already existed before that. Why then shall these procedures be made?

Claim 12 contradicts Article 6.4(a) of the PCT Patent Regulations, in accordance to which any dependent claim which refers to more than one other claim shall refer to such claims only as to alternatives. The Applicant shall amend the claim to bring it in correspondence with the above rule. The same relates to claims 18-19, 74-75 and 94.

Further, claim 12 contradicts claims 1-11. It is evident from the application materials (see pp.36-37 of the disclosure) that a delay in an activation time can lead to increase in the force of contraction as well as to its decrease. In claims 1-11 it is indicated that the field is applied in such a way as to reduce the mechanical activity at the portion and to reduce the force of contraction. Therefore, claim 12 shall include indication of such a time delay which would lead to reduction in the mechanical activity. The Applicant shall amend claim 12 taking into account the above.

Furthermore, known is a method of eliminating constipations in case of a hemorrhoid by using spasmolytic agents and/or darsonvalization, which leads to relaxation of a muscle wall and elimination of constipations (Боголюбов В.М., Курортология и физиотерапия, М., Медицина, 1985, т.2, с.420 (Bogolyubov V.M., Balneology and Physiotherapy, M, Medicine, 1985, v.2, p.420)).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle by applying to it a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

Therefore the invention claimed in claim 9 is not inventive in view of these documents.

5. In accordance with Rule 19.5.1(1) of the Rules, the possibility to implement the purpose to be served by the claimed subject-matter and indicated by the Applicant shall be confirmed. In this connection, the Examiner notes that examples confirming the

possibility to implement the purpose indicated in claims 13-14 are absent from the application materials. To make claims 13-14 complying with the requirement of industrial applicability, the Applicant shall present examples wherein the electric field applied to a first portion of a GI tract and increasing the force of contraction at this portion and the electric field applied to a portion of the GI tract downstream from said first portion and decreasing the force of contraction increase the motility of the GI tract.

Furthermore, the Examiner notes that increasing the motility of a GI tract by applying an electric current is described in RU 2055606 C1, 10.03.1996.

It is also known that it is possible to increase the amplitude of the action potential of a cell, including a smooth muscle cell, and thus to increase its force of contraction by applying to it a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

Therefore the invention claimed in claims 13-14 is not inventive in view of these documents.

6. The Examiner notes that the feature "substantially" mentioned in claim 17 is unidentifiable. This feature shall, in accordance with Rule 19.4(3) of the Rules, be cancelled.

7. The Examiner notes that a method of selectively exciting only a layer of muscle in a smooth muscle having a plurality of muscle layers with different fiber orientation, comprising applying an electric field which excites a second layer of the muscle is described in RU 2075980 C1, 27.03.1997.

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle by applying to it a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

Therefore the invention claimed in claim 20 is not inventive in view of these documents.

8. The Examiner notes that a method of selectively exciting only a layer of muscle in a smooth muscle having a plurality of muscle layers with different fiber orientation, comprising applying an electric field which excites a second layer of the muscle is described in RU 2075980 C1, 27.03, 1997.

It is also known that it is possible to increase the amplitude of the action potential of a cell, including a smooth muscle cell, and thus to increase its force of contraction by applying to it a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

Therefore the invention claimed in claim 21 is not inventive in view of these documents.

9. The technical problem solved by the method claimed in claim 22 is unclear. Why shall a smooth muscle be activated if such an activation is then immediately supported? The Applicant shall amend claim 22 on the basis of the application materials.

10. The Examiner notes that claim 56 contradicts the disclosure (see p. 30). In claim 56 it is indicated that the claimed method is used for aiding the examination of a GI tract, e.g., of a portion adjacent a bile duct. On p. 30 of the disclosure it is indicated that this method is used for aiding the exit of gall bladder stones into the intestines. Therefore, the Applicant shall specify the purpose served by the claimed method.

Furthermore, the Examiner notes that it is known to introduce a probe into a GI tract, e.g., for endoscopic examination, simultaneously with reducing a smooth muscle tone by administering drugs for aiding the implementation of diagnostic procedures (Савельев В.С. и др., Руководство по клинической эндоскопии, М., Медицина, 1985, с.21 (Saveliev V.S. et al., Guidebook on Clinical Endoscopy, M., Medicine, 1985, p.21)), as well as by delivering air to smooth GI tract folds when examining a GI tract (see Савельев В.С. и др., Руководство по клинической эндоскопии, М., Медицина,

1985, c.35 (Saveliev V.S. et al., Guidebook on Clinical Endoscopy, M., Medicine, 1985, p.35)).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle and the smooth muscle tone, which, in turn, results in its relaxation, by applying to the tissue a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, c. 348-350, 376 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350, 376)).

Therefore the method claimed in claims 56-57 is not inventive in view of these documents.

11. With respect to claims 58-59 and 61-62, the Examiner notes that known is a method of advancing a probe in a GI tract, e.g., for the implementation of endoscopic examination (see Савельев В.С. и др., Руководство по клинической эндоскопии, М., Медицина, 1985, c.21 (Saveliev V.S. et al., Guidebook on Clinical Endoscopy, M., Medicine, 1985, p.21)). The claimed method is distinguished from the known one in that the probe is advanced by using electric fields which are applied in such a way as to provide movement of the probe in the desired direction. However, the use of electric fields which cause the intestines to transport the source of an electric field in the desired direction by alternate action on longitudinal and circular muscles of a GI tract is described in RU 2075980 C1, 27.03.1997. Therefore, the Applicant's proposal relates to creation of a means consisting of known parts which are selected and connected on the basis of known rules and recommendations, with the achieved technical result being caused only by the known properties of the parts. Thus, the Applicant's proposal cannot be regarded as involving an inventive step (see Rule 19.5.3 of the Rules).

12. With respect to claims 68 and 69, the Examiner notes that known is a method of treatment of premature interruption of pregnancy (i.e., of the same purpose) by relaxing an uterus by means of an electric current supplied by using electrodes applied on the front abdominal wall and sacrum. The known method provides reduction in the uterus tone and disappearance of contraction waves (SU 831131, 19.04.1979). The method

claimed in claims 68-69 is distinguished from the known one in that a portion of the uterus suspected of generating undesirable activation signals is determined and a local desensitizing electrical field is applied to the uterus muscle around the suspected portion (claim 68) or to the suspected portion (claim 69), whereby the propagation of undesirable activation signals on the whole uterus is inhibited. However, it is known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, by applying to it a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)), whereby the electrical activity on the portion wherein the field is applied is blocked. The detection of scar tissue, inflamed tissue, etc., which, in accordance with the Applicant's idea, cause undesirable activation signals, is well known in the art and can be realized, e.g., by visual inspection or electromyographically. Therefore, the Applicant's proposal relates to creation of a means consisting of known parts which are selected and connected on the basis of known rules and recommendations, with the achieved technical result being caused only by the known properties of the parts. Thus, the Applicant's proposal cannot be regarded as involving an inventive step (see Rule 19.5.3 of the Rules).

13. The Examiner notes that the term "local activation" mentioned in claim 70 is unidentifiable. The Applicant shall, according to Rule 19.4(3) of the Rules, either cancel this feature, or specify it on the basis of the original application materials.

Furthermore, the use of an electric field for stimulating labor using external and internal electrodes and a feedback sensor controlling the force of birth pains is described in SU 553977, 12.03.1975.

It is also possible to increase the amplitude of the action potential of a cell, including a smooth muscle cell, by applying to it a constant electric current, whereby the contraction force of said cell is increased (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle and the smooth muscle tone, which, in turn, results in its relaxation, by applying to the tissue a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350, 376 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350, 376)).

Furthermore, increasing or reducing the contractive activity of a smooth muscle, according to the time of the applied stimulation, after the appearance of an active potential is also described in the prior art (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с.376 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, p. 376)).

Therefore, the invention claimed in claim 70 is not inventive in view of these documents.

14. The Examiner notes that known is a method of medical treatment of premature interruption of pregnancy (i.e., of the same purpose) by relaxing an uterus by applying an electric current supplied by electrodes applied on the front abdominal wall and sacrum. The known method provides **reduction of the uterus tone** and disappearance of contraction waves (SU 831131, 19.04.1979).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle and the smooth muscle tone, which, in turn, results in its relaxation, by applying to the tissue a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350, 376 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350, 376)).

Therefore, the method claimed in claim 79 is not inventive in view of these documents.

15. The Examiner notes that known is a method of medical treatment of premature interruption of pregnancy (i.e., of the same purpose) by relaxing an uterus by applying an electric current supplied by electrodes applied on the front abdominal wall and

sacrum. The known method provides **reduction of the uterus tone** and disappearance of contraction waves (SU 831131, 19.04.1979).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle and the smooth muscle tone, which, in turn, results in its relaxation, by applying to the tissue a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350, 376 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350, 376)).

Known is the use of electrodes introduced into the uterus for carrying out electrostimulation sessions (SU 386634, 06.08.1971, SU 553977, 12.03.1975).

Therefore the method claimed in claim 80 is not inventive in view of these documents.

16. The Examiner notes that in claims 89-90 the feature defining the place of applying electrodes to a vein is too broad and therefore does not correspond to the essence of the invention. On p.35 of the disclosure it is indicated that large veins are meant. The Applicant is requested to specify this feature on the basis of the original application materials.

17. In claims 91-92 the feature defining the place of applying electrodes to an artery is also too broad and therefore does not correspond to the essence of the invention. On p.35 of the disclosure it is indicated that large arteries are meant. The Applicant is requested to specify this feature on the basis of the original application materials.

The Examiner also notes that known is the use of electric current acting on sympathetic nerves for expanding and constricting arteries (Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с.115 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, p. 115)).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle and the smooth muscle tone, which, in turn, results in its relaxation, by applying to the tissue a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350, 376 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350, 376)).

It is also possible to increase the amplitude of the action potential of a cell, including a smooth muscle cell, by applying to it a constant electric current and to increase the contraction force of said cell (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350)).

Therefore the method claimed in claims 91-92 is not inventive in view of these documents.

18. The Examiner notes that known is a method of determining and localizing abnormal constriction of a vessel followed by treating such abnormally constricted lumen (see RU 1827793 A1, 10.05.1995).

It is also known that it is possible to reduce the excitability of a tissue, including a smooth muscle tissue, and thus the contraction activity of the muscle and the smooth muscle tone, which, in turn, results in its relaxation, by applying to the tissue a constant electric current (see Бабский Е.Б. и др., Физиология человека, М., Медицина, 1972, с. 348-350, 376 (Babsky Ye. B. et al., Physiology of Man, M., Medicine, 1972, pp. 348-350, 376)).

Therefore the method claimed in claim 93 is not inventive in view of these documents.

19. The Examiner notes that the technical essence of the invention claimed in claim 94 in its part concerning applying a non-excitatory electric field to a portion of a heart is unclear. Any information concerning the technical result achieved when applying the field to the heart is absent from the application materials. Therefore it is unclear how,

where and why the field is applied. In the absence of such information the invention claimed in claim 94 cannot be considered complying with the requirement of industrial applicability.

20. The Examiner notes that claim 100 do not comply with the principle of invention unity. In accordance with Rule 13.2 of the PCT Regulations, a group of inventions meets the requirement of invention unity only when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. An electric field and the place where it is applied, i.e. a smooth muscle, are the special technical features uniting the claimed group of inventions. However, in the invention of claim 100 the electric field is applied to hormone producing cells which are not smooth muscle cells. Therefore, claims 100-103 shall, with the above taken into account, be cancelled from the claims.

21. The Examiner notes that the words "for example" mentioned in claim 106 can lead to ambiguous interpretation of the scope of protection. Therefore, the Applicant shall delete these words from claim 106.

In accordance with Rule 3.3.2.5(1) of the Russian Patent Rules, a dependent claim shall comprise development and/or specification of the features of an independent claim by features defining the invention in a specific case of its implementation or use. Dependent claim 108 does not correspond to said Rule. I.e., in accordance with claim 106, a non-excitatory field is applied to a portion of an organ, while in claim 108 it is indicated that an excitatory field is applied to a portion of the organ. Therefore, claim 108 contradicts claim 106. This contradiction shall be eliminated by the Applicant.

The Examiner notes that the term "an activated profile" mentioned in claims 106-112 is unidentifiable. The Applicant shall either cancel this feature from the claim, or indicate a document, published before the priority date of the present application, wherein this term was explained.

With respect to the claimed devices, the Examiner notes the following.

After analyzing the claims relating to the apparatus according to independent claim 23, the Examiner notes that claim 25 is not properly drafted. In claim 25 it is indicated that the electrification at each electrode is responsive to its local electric activity. It is unclear what electric activity is meant in the claim. May be, the electric activity of some other object is meant?

The same relates to claim 30, i.e. it is unclear what mechanical activity is meant in this claim and from what it is selected.

Claim 34 contradicts claim 23, i.e., in independent claim 23 it is indicated that a non-excitatory electric field is generated, while in accordance with claim 34 an exciting electric field is applied. The Applicant is requested to make corresponding amendments.

It is unclear from the application materials why two perpendicular electric fields are generated in the apparatus according to claim 36.

The Examiner asks the Applicant to explain the essence of the invention claimed in claim 43, i.e., which remote regions of the uterus are meant and how are electrodes attached to these remote regions.

The end of claim 83 shall, in the Examiner's opinion, be better presented as follows: "electrifies the electrode for generating a local non-excitatory electric field".

In the Examiner's opinion, the title of claim 95 is incorrect. The application concerns devices for controlling a smooth muscle, therefore, claim 95 shall relate, e.g., to an apparatus for controlling a heart smooth muscle. Furthermore, a heart muscle is not fully smooth.

The Examiner asks the Applicant to explain what is the external control which activates a controller.

Claims 104-105 do not, in the Examiner's opinion, comply with the principle of invention unity because "the output of a gland" cannot relate to a smooth muscle.

The features "a mechanical activation profile", "a particular activation profile", "the sensed local mechanical activity" mentioned in claims 112-113 are, in accordance with Rule 19.4(3) of the Rules, unidentifiable and shall be explained by the Applicant.

Therefore, the Applicant shall analyse the Examiner's arguments, to amend the claims and disclosure in accordance with the above and present his opinion on the raised questions without going beyond the original application materials.